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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,401	02/12/2002	Ian Stuart Pardoe	S1011/20127	7651

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EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1654	9

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	10/049,401	PARDOE, IAN STUART	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-33* is/are pending in the application.

4a) Of the above claim(s) *13,14 and 20-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group I, claims 15- 19 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that claims 13 and 14 were inadvertently omitted from the election requirement. These claims are properly placed in Group III as they are drawn to a method for treating a viral infection via a water-soluble extract of Palmaira. Thus, these claims are withdrawn from consideration on the merits. Further, claims 10-12 were not placed in groups because it cannot be determined what group these claims belong to since claim 10 is dependant upon a canceled claim. Thus, the Examiner will leave these claims non-withdrawn and leave the Applicant to either cancel these claims, or make them dependant upon an elected claim (please also see rejection under 35 U.S.C. 112 Second paragraph *infra*).

Claims 10-12 and 15-19 were examined on the merits.

Priority

The Specification fails to make the necessary reference to the prior 371 application as well as the foreign priority document. Applicants are required to submit a statement following the Title of the Invention which reads 'This is a 371 of PCT/GB00/01233 which claims benefit of priority to Application number GB 0007596.2 filed in the United Kingdom on 4/01/1999'.

Specification

The disclosure is objected to because of the following informalities:

Page 3, on the last line of the page, recites 'Dulsk'. The proper spelling is 'Dulse'. This appears to be a minor typographical error. The correct spelling is found on page 4, third paragraph.

Appropriate correction is required.

Claim Objections

Claim 15 is objected to because of the following informalities:

Claim 15 recites 'comprising water-soluble extract...'. This phrase should correctly read 'comprising ***a*** water-soluble extract'. This is considered a minor grammatical error.

Claim 15 further recites '...effective against viruses...'. While it is understood that Applicants mean that the composition is effective for treating viruses, or inhibiting viruses (in light of the Specification), the Instantly recited claim is awkward. It is suggested that this phrase be changed to 'effective for treating' in order to overcome this objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-12 are dependant upon a canceled claim. Thus, the metes and bounds of the claims cannot be properly determined. Applicant is asked to either cancel the claims, or amend these claims to depend upon a pending claim in order to overcome this rejection. These claims will not be treated further on the merits since the subject matter of the claims as a whole cannot be determined. Please note that if Applicants resubmit these claims in independent form, or to depend upon a pending claim, the claims may be subject to restriction.

Claim 16 recites 'A composition is adapted for administration orally, intravenously, or topically.' The metes and bounds of the composition are not delineated because the exact nature of the composition has not been claimed. Because claims 17 and 18 are directly or indirectly dependant upon claim 16, these claims are also rejected for not being fully delineated. Applicant is asked to either 1) cancel the claim 2) amend the claim to depend upon claim 15 or 3) amend the claim to recite an independent claim. Please note that any new dependant claim may be subject to restriction. In order to facilitate examination of this claim, the claim was

examined as if it were dependant upon claim 15, as were claims 17 and 18. Applicant may wish to amend the claim to reflect that claim 16 is dependant upon claim 15. For example, the claim may be amended to read 'The composition of claim 15, wherein said composition ...'. However, it is further noted that claim 16 recites 'is adapted'. This phrase, as used in the claim is indefinite because the metes and bounds of this term are not clearly delineated. As such, the composition is not fully described. Does 'adapted' mean that the composition is further purified? Does 'adapted' mean that the extract is added into a carrier? Does 'adapted' mean that the concentration of the extract is modified? The ordinary artisan would have trouble ascertaining the exact meaning of 'adapted' and therefore this phrase is indefinite. It is suggested that Applicant amend this claim (in addition to the suggested amendments *supra*) to recite an exact descriptor which 'adapts' the composition such as a carrier; i.e., 'The composition of claim 15 for administration orally, intravenously or topically, further comprising a carrier selected from the group consisting of an orally acceptable carrier, an intravenously acceptable carrier and a topically acceptable carrier'.

Claims 17 and 19 also recite 'adapted'. Therefore, these claims are rejected for the same reasoning set forth for claim 16 with regard to the term 'adapted'. Please follow suggestions outlined *supra*.

Claim 18 recites '...comprising a 200 mg. capsule...'. While it is understood what a 200 mg capsule is, it is believed that this is contrary to what the Specification teaches.

Thus, the claim is indefinite. The specification teaches that the extract may be delivered orally via capsules, but does not describe a 200 mg capsule, and therefore the claim lacks antecedent basis in the Specification. It is thought that Applicants intend to claim wherein the composition is contained in a capsule. Therefore, it is suggested that Applicant amend the claim to recite: " A composition according to claim 17, wherein said composition comprises 200 mg of said extract, and wherein said composition is contained in a capsule'. (Please note that this is merely a suggestion: any suitable means for overcoming the rejection will be considered).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Briand (US 5,508,033). Claims 15-17 and 19 are drawn to a pharmaceutical composition comprising a water-soluble extract of *Palmaria palmata*. Claims are further drawn to wherein the composition is 'adapted' for ingestion orally,, intravenously or

topically, and wherein the composition is adapted for administration in the treatment of viruses of the herpes family.

Briand (US 5,508,033) disclosed algae extracts which displayed antioxidant activity (Abstract and Table 1, col.5). Specifically, Briand taught that an extract could be prepared from *Palmaria palmata* which consisted of extracting *P.palmata* with a hydroalcoholic mixture containing 180 ml of water and 20 ml of alcohol (col.2, Example 6). This extract was stirred and filtered. Because the product was obtained in an aqueous extraction solvent, the product was 'water-soluble' as claim 15 states.

The term 'adapted' is not fully defined, nor fully understood within the boundaries of the claims as discussed *supra* under 35 USC 112 Second paragraph. Because the solution was filtered, leaving the active material, it is deemed that this material was 'adapted' from it's previous form (in a non-homogenous mixture). Therefore, it is deemed that the final form of the product obtained from extraction, as disclosed by Briand, could have been administered orally, intravenously or topically or used for treatment thereby anticipating claims 16, 17 and 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briand (US 5,508,033). The nature of claims 15-17 and 19 were discussed *supra*. Claim 18 is drawn to wherein the composition of claim 17 comprises 200 mg of the extract contained in a capsule.

The teachings of Briand (US 5,508,033) were discussed *supra*. Briand did not specifically teach wherein 200 mg of the extract were contained in a capsule. Briand did however teach that the compositions could have been used for a pharmaceutical purpose (See claim 1 for example). Briand further taught that the algae extracts were administered orally to ascertain their toxicities. The extracts were found to be non-toxic (col.6, lines 59-62).

One of ordinary skill in the art would have been motivated to encapsulate the *Palmaria palmata* extract in order to ease the oral delivery of the extract. It was clear from Briand that the *Palmaria palmata* extract was useful as an anti-radical and that it

was non-toxic when orally administered. The selection of a capsule would have therefore been a matter of judicious selection on the part of the ordinary artisan; a suitable means for delivering and storing the ingredients. Alternatively, the ordinary artisan would have been motivated to have incorporated the extract into a capsule to ease topical delivery of the extract. It was taught by Briand that the compositions were useful to treat skin ailments such as burns and lesions. Incorporation of the extract into a capsule would have offered a convenient way of packaging individual aliquots of extract which were easily stored and carried.

Although Briand did not specifically teach 200 mg of extract, the ordinary artisan would have been motivated to have varied the amount of extract according to the patient's needs (i.e., regular -vs- extra strength). Varying individual components in a composition was routine in the art of pharmacology. Such adjustments were considered routine optimization of a result effective variable.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

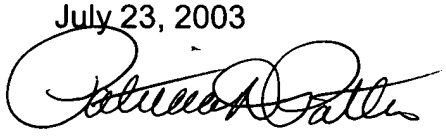
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. The official After final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

July 23, 2003



Patricia Patten